

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:NDA 20582/S002

MICROBIOLOGY REVIEW(S)

Theodoraki

JAN 14 1999

REVIEW FOR HFD-170
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW OF CBE SUPPLEMENT
11 January 1999

A. 1. Lead NDA 17-398/SCM-012 and

NDA 13-132/	NDA16-750/SCS-016	NDA 17-692/S-013
NDA 18-776/SCM-024	NDA 20-214/SCM-009	NDA 20-328/S-003
NDA 20-582/S-002		

APPLICANT:

Organon, Inc.
375 Mt. Pleasant Avenue
West Orange, NJ 07052

2. PRODUCT NAME: Regonol® (pyridostigmine bromide injection, USP) and 7 Others
3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
The products are injectable preparations.
4. METHODS OF STERILIZATION:
5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE INDICATION:
The products are intended for a variety of indications.

- B. 1. DATE OF INITIAL SUBMISSION: 20 November 1998
2. DATE OF AMENDMENT: (none)
3. RELATED DOCUMENTS: ANDA 89-624
ANDA 80-997
4. ASSIGNED FOR REVIEW: 14 December 1998

C. REMARKS: The submission seeks approval for a new stopper processor to be used for preparation of product packaging components.

D. CONCLUSIONS: The application is recommended for approval on the basis of sterility assurance.

/S/

Paul Stinavage, Ph.D.

11 January 1999

PHZ 1/14/99

cc: Original Lead NDA 17-398/SCM-012 and

NDA 13-132	NDA 16-750/SCS-016	NDA 17-692/S-013
NDA 18-776/SCM-024	NDA 20-214/SCM-009	NDA 20-328/S-003
NDA 20-582/S-002		

HFD-170/A. D'sa/M. Theodorakis

HFD-805/Consult File/Stinavage

HFD-800/S. Lange

Drafted by: P. Stinavage, 11 January 1999

R/D initialed by P. Cooney